Improving the safe administration of injectable medication

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Chapter 1

General Introduction

Diana (fictional case)

Diana is a nurse who has been working for over ten years in the internal medicine department of a general hospital. She has taken additional courses on lung diseases and currently she is an expert in her department. Today, she is taking care of Mrs Walters who has been admitted due to an exacerbation of her COPD. Mrs Walters suffers from shortness of breath and the physician has prescribed a furosemide infusion. Diana automatically notices the medication order in the Electronic Health Record (EHR) system. This system was implemented two years ago in the hospital, together with a barcode medication administration (BCMA) system. However, at the moment only one of the three BCMA systems has working Wi-Fi, so Diana has to wait to use a device. In the meantime, Diana prepares the medication according to the guideline and calculates the right infusion rate. She is ready to administer the medication at 4 p.m. when a physician enters the room and poses a few questions. After that, Diana continues with the medication administration and sets the infusion pump at a rate of 9.2 ml/hour. The evening shift is taken over by her nursing colleague Noelle, who checks on each patient at around 6 p.m. She suspects that the infusion rate for Mrs Walters is too high (normally the rate is around 1 or 2 ml/hour). Noelle recalculates the infusion rate, ending up with 1.2 ml/hour. She immediately adjusts the infusion pump and informs Mrs Walters that something went wrong. She also reports the incident in a digital report. The next day Diana returns to the department and reads about the incident. How could this have happened? Mrs Walters had to make several visits to the toilet, but luckily she has not sustained any permanent harm. However, Mrs Walters needs to stay an extra day in the hospital because of this incident.

Patient safety, Safety-I and Safety-II

Patient safety is still a serious healthcare issue, despite global efforts in the past 30 years.[1] Patient safety comprises the reduction and prevention of risks, errors and harm that occur to patients during the delivery of healthcare.[2] Currently, there are two perspectives when looking at patient safety: Safety-I and Safety-II.[3] Safety-I has been the standard for years and most research is done from a Safety-I perspective. It sees patient safety as a state in which 'as few things as possible go wrong', but when something goes wrong, it can result in adverse events (AEs).[3] According to Baker et al., an AE is an unintended injury that results in prolongation of a hospital admission, temporary or permanent disability or death and is caused by healthcare management instead of the patient's disease.[4] Safety-II is relatively new in healthcare and focuses on understanding how work that often goes well is done in clinical practice. It also

focuses on understanding resilience and variability in the process.[3] The main differences between Safety-I and Safety-II are that Safety-II focuses on all healthcare outcomes instead of only the negative outcomes (e.g. AEs), is more proactive and sees humans as a part of the solution instead of part of the problem.[3]

Safety-I perspective on injectable medication administration

Worldwide, approximately 43 million AEs occur every year,[5] and one in every 20 patients admitted to hospitals experiences preventable AEs.[6] The most common types of AEs occurring in hospitals are caused by medication, and are known as adverse drug events (ADEs).[6-8] Furthermore, studies show that 16-34% of all ADEs are caused by preventable medication errors.[6] The consequences of ADEs and medication errors may be considerable for a patient, such as prolonged admission or even death. The consequences of ADEs for society at large include additional costs, of up to 100,000 euros per error.[9]

In particular, ADEs with injectable medication have a higher risk of patient harm compared with non-injectable medication. Injectable medication consists of intravenous infusions and subcutaneous or intramuscular injections. Over 90% of all hospitalized patients receive some form of infusion therapy, including injectable medication.[10] Approximately 10% of all injectable medication administrations are associated with at least one error.[11] The high risk of patient harm is caused by the fact that this type of medication has an immediate therapeutic effect and can reach dangerous drug levels in a short period of time. So when injectable medication is not administered correctly, the error is often irreversible.

Keers et al. explored the causes of medication administration errors (MAEs), taking a Safety-I perspective. They pointed out that a strong theoretical focus is needed regarding the nature and complexity of these MAEs.[8] Then the key risk factors for these errors can be studied in order to develop multifaceted interventions.

Safety-II perspective on injectable medication administration

The injectable medication administration protocol can never cover all clinical practice situations. This means that in daily practice, circumstances may mean nurses are not able to follow the proceedings as intended and therefore need to adjust them to achieve their goal. This creates variation in the process. Nevertheless, administering injectable medication almost always goes well. Research on the injectable medication

administration process from this Safety-II perspective is relatively new and scarce. For example, Kaya et al. showed that Safety-II can be used to understand the complex process, in particular to reveal the non-linear interactions between different proceedings in a visual model.[12] Furthermore, another recent study shows some examples of process variability, for instance when multiple medication types cannot be administered at the same time through the same access point, when medications are infused faster, and when the thoroughness of the double check by a second nurse differs.[13] These situations can create variability further along in the process and then nurses might have to adjust or work around the protocol in order to administer the medication correctly.

Injectable medication administration in nursing practice

Administering injectable medication is a primary task of nurses. In the past decade, four main interventions changed the role of nurses in the medication administration process. First, to enhance knowledge about medication, training-related interventions have been applied, such as appointing and training dedicated nurses or arranging training led by pharmacists.[14] Second, hospitals have implemented guidelines to enhance uniformity in the medication administration process. Third, multifaceted interventions have been implemented to prevent interruptions during injectable medication administration.[15] As a consequence, there is more awareness about interruptions as a cause and contributor of medication errors.[8, 16] Furthermore, there is more awareness about multitasking and learning how to deal with interruptions.[15, 17] Fourth, information technology is increasingly used to support nurses during injectable medication administration.[14, 18] For example, a growing number of hospitals have implemented barcode medication administration (BCMA) systems. By scanning the barcode of a patient's wristband and/or the medication label, the system electronically assures that 'the right patient' gets 'the right medication'. These BCMA systems have effectively reduced some, but not all, types of medication errors.[18]

The four interventions are also noticeable in the clinical practice of our fictional nurse, Diana. She followed extra training to become an expert, works in line with the current guidelines, is aware that a physician interrupted her, and uses a BCMA system in the administration of injectable medication.

Complex process

In their efforts to improve the safe administration of injectable medication, most studies focused on single aspects of the process, for example, the organization (protocols),

tools (BCMA), and the nurses (knowledge). Yet it is widely acknowledged that ADEs are often caused by an accumulation of multiple failures in the system rather than one single event.[19] The medication process is complex,[20] and targeting just one aspect of this process is often too restrictive. A complex process contains large numbers of interacting elements, which are often nonlinear and dynamic.[21] The complexity may be especially present in unexpected interactions between the process elements. The more unexpected the interactions, the more difficult it will be to predict how processes will develop, and the more challenging it will be to improve medication safety in the long term. So it is important to understand the whole injectable medication administration system, including the complexity, in order to develop interventions.[22]

The Dutch situation

In the Netherlands, one of the first steps to improve safety in the medication administration process was the introduction of a safety management system programme. This programme was implemented between 2008 and 2012 in all Dutch hospitals and consisted of ten safety themes. One of the themes was 'safe preparation and administration of injectable medication'. It included two protocols, one for preparing and one for administering injectable medication. Today, both protocols are still the prevailing protocols; they contain 35 and 25 proceedings respectively for the safe preparation and administration of injectable medication. All proceedings are based on the 'five rights' of safe medication administration (right patient, right medication, right dose, right route, right time).[20] The implementation consisted of national conferences, a guide including advice and protocols, and training sessions about the safe preparation and administration of injectable medication. The aim of the theme was, from a Safety-I perspective, to reduce risks, errors and harm by achieving 100% compliance with both protocols.

In 2011 and 2012, Schilp et al. evaluated the extent to which the theme 'safe preparation and administration of injectable medication' had been implemented.[23] The study showed that protocol compliance was achieved in only 19% of the 2,154 observed administrations. Of the nine most important and identifiable proceedings in the protocol, the lowest compliance was observed in the following three: conducting hand hygiene, identifying the right patient and the check by a second nurse.[23] These findings gave rise to questions such as: what are the reasons for poor compliance, is the protocol feasible or too complex to follow in daily practice, and what barriers and facilitators are related to protocol compliance?

SEIPS 2.0

To understand the whole injectable medication administration system, including the complexity, the Systems Engineering Initiative for Patient Safety (SEIPS) model can be used as a theoretical framework.[22] The model was introduced in 2006 (SEIPS 1.0) and revised in 2013 (SEIPS 2.0).[24] By using SEIPS, we can understand interactions between the work system, processes (e.g. protocol compliance) and outcomes (e.g. MAEs).[22] The model includes risks related to the person (e.g. knowledge or motivation), risks related to the internal or external environment (e.g. noise or the design of departments), risks related to the organization (e.g. teamwork or policies), risks related to tools and technologies (e.g. devices or resources) and risks related to tasks (e.g. variety of tasks or autonomy). Furthermore, an adaptation phase was incorporated in the SEIPS 2.0 model.[24] With this phase, the model takes into account the fact that processes are not linear but dynamic, and that nurses need to react and adapt constantly to unexpected situations in the process (e.g. complexity). Therefore, the adaptation phase is in line with the Safety-II perspective. The Safety-I perspective is mainly reflected in the processes and outcomes phases of the SEIPS 2.0 model (Figure 1).

Hence, by describing the aspects of the work system in addition to processes and outcomes, SEIPS 2.0 is best suited to detail the whole routine clinical process in which Diana needs to function in order to ensure that the right injectable medication is administered in the right dose, by the right route, at the right time and to the right patient.

Objective

The aim of this PhD thesis is to gain a deeper understanding, from a Safety-I and Safety-II perspective, of the complex process of injectable medication administration by hospital nurses. The SEIPS 2.0 model was used as a theoretical base. By gaining a deeper understanding, we aim to reduce the risk for future patients of experiencing an injectable medication administration error during their hospital stay. To achieve this aim, we formulated two research questions:

1. What is the current nurse compliance with the protocol for safe injectable medication administration in hospitals and what is the current frequency of adverse drug events?

2. Which interactions in the work system and adaptations occur in nursing practice during injectable medication administration?

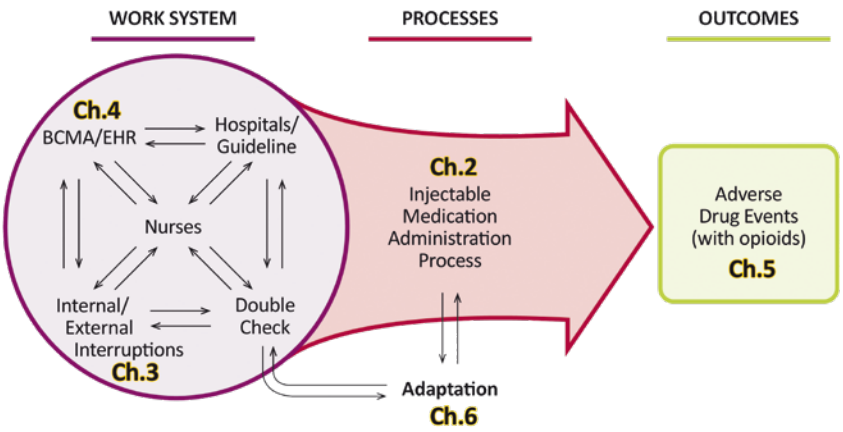

Figure 1 The injectable medication administration process from a Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 perspective, incorporating the chapters of this PhD thesis. BCMA = BarCode Medication Administration, EHR = Electronic Health Record

Thesis outline

To answer these questions, we conducted five studies, which are described in **Chapters 2-6**. The first research question is addressed in **Chapters 2, 4 and 5** and the second research question in **Chapters 2, 3 and 6**. Each chapter focuses on one specific aspect in the SEIPS 2.0 model and all chapters focus on the nurse as the 'person' at the centre of the work system. Furthermore, each chapter also describes other relationships within the SEIPS 2.0 model.

Chapter 2 focuses on the process of injectable medication administration. In this observational study, we determined nurse compliance with the protocol for safe injectable medication administration. The results were compared to the first evaluation study (conducted in 2011/2012) to understand whether compliance has improved over time. Moreover, we assessed which improvement strategies hospitals implemented regarding all aspects of the SEIPS 2.0 work system.

Chapter 3 focuses on the external environment in which nurses administer injectable medication. In this observational study, we analysed the frequency, causes and factors associated with interruptions during injectable medication administration in hospitals. The data used in this study were collected during both the first and the

second evaluation of the 'safe preparation and administration of injectable medication' theme.

Chapter 4 focuses on technology used by nurses when administering injectable medication. In this cross-sectional study, we aimed to extract real-time information about nurse compliance with the protocol for safe injectable medication administration in order to create a continuous feedback loop. Therefore, we assessed whether it is feasible to monitor nurse compliance with the protocol by reusing routinely registered EHR data. We interviewed healthcare professionals about the availability of data elements in their hospitals' EHR system.

Chapter 5 focuses on undesirable outcomes in the medication process: adverse drug events (ADEs). In this study we conducted a post-hoc analysis of data collected during three Dutch retrospective patient record review studies. The goal was to provide a detailed description of the underlying nature of ADEs. This chapter focuses on one specific drug type, namely opioids, because opioids are often given by nurses as injectable medication and they have fast therapeutic effects with possibly severe or fatal patient outcomes.

Chapter 6 focuses on adaptation by nurses in the context of injectable medication administration. In this qualitative study, we focused on one of the protocol proceedings that is most likely to be omitted: the double check during injectable medication administration. We determined the extent to which work-as-imagined according to the protocol matched work-as-done in current clinical nursing practice.

Finally, the general discussion is presented in **Chapter 7**. In this chapter we answer the two main research questions, discuss the methodological considerations, and end with recommendations for future research and for current and future nurses who will be administering injectable medication.

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